

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATE OF AMERICA

§

v.

Case No. 22-CV-1159

§

ANDREW SINCLAIR / B4B EARTH TEA
LLC / B4B CORP

Feb 6, 2024

I

ADMISSIONS AND DENIALS

1. The Defendant admits to manufacturing an herbal product called Earth Tea retail for \$60 and is sold as a Natural supplement. Defendant denies deceptive advertising, misinformation, incompetence and posing a risk to public health in paragraph 1 of the complaint . The Defendant does not know whether the other information in paragraph 1 of the complaint is true or false.
2. The Defendant denies the allegation in paragraph 2 of the complaint
3. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 3 of the complaint
4. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 4 of the complaint
5. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 5 of the complaint
6. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 6 of the complaint
7. The Defendant admits to paragraph 7 of the complaint
8. The Defendant denies acting in concert with others. The Defendant admits to paragraph 8 of the complaint

9. The Defendant denies allegations in paragraph 9 of the complaint
10. The Defendant admits to acting alone allegations in paragraph 10.
The Defendant denies representation allegations to treat, prevent, cure or mitigate Covid-19 in paragraph 10. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 10 of the complaint.
11. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 11 of the complaint. The Defendant denies unfair or deceptive acts or practices in or affecting commerce allegations in paragraph 11 of the complaint
12. The Defendant denies allegation in paragraph 12 of the complaint
13. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 13 of the complaint. The Defendant denies false advertising allegation in paragraph 13
14. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 14 of the complaint
15. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 15 of the complaint
16. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 16 of the complaint. The Defendant denies deceptive act allegation in paragraph 16 of the complaint
17. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 17 of the complaint
18. The Defendant denies allegations in paragraph 18 of the complaint
19. The Defendant denies Drug allegation in paragraph 19, The Defendant lack sufficient information to determined the truth of the allegations in paragraph 19 of the complaint
20. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 20 of the complaint
21. The Defendant denies allegations in paragraph 21 of the complaint

22. The Defendant denies Drug allegation in paragraph 22 of the complaint, The Defendant lack sufficient information to determined the truth of the allegations in paragraph 22 of the complaint
23. The Defendant admits to paragraph 23. The Defendant denies formerly b4bcorp.com allegation in paragraph 23 of the complaint
24. The Defendant denies allegations in paragraph 24 of the complaint
25. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 25 of the complaint
26. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 26 of the complaint
27. The Defendant Denies allegations in paragraph 27 of the complaint
28. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 28 of the complaint
29. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 29 of the complaint
30. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 30 of the complaint. The Defendant denies all deceptive allegations in paragraph 30 of the complaint
31. The Defendant denies allegations in paragraph 31 of the complaint
32. The Defendant denies allegations in paragraph 32 of the complaint
33. The Defendant denies allegations in paragraph 33 of the complaint.
34. The Defendant denies allegations in paragraph 34 of the complaint
35. The Defendant denies allegations in paragraph 35 of the complaint
36. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 36 of the complaint.

37. The Defendant denies the allegations in paragraph 37 of the complaint
38. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 38 of the complaint.
39. The Defendant denies the allegations in paragraph 39 of the complaint
40. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 40 of the complaint.
41. The Defendant denies the allegation in paragraph 41 of the complaint
42. n/a
43. The Defendant Denies allegations in paragraph 43 of the complaint
44. The Defendant Denies allegations in paragraph 44 of the complaint
45. The Defendant Denies allegations in paragraph 45 of the complaint
46. The Defendant Denies allegations in paragraph 46 of the complaint
47. The Defendant Denies allegations in paragraph 47 of the complaint
48. The Defendant Denies allegations in paragraph 48 of the complaint
49. The Defendant Denies allegations in paragraph 49 of the complaint
50. The Defendant Denies allegations in paragraph 50 of the complaint
51. n/a

52. The Defendant Denies allegations in paragraph 52 of the complaint
53. The Defendant Denies allegations in paragraph 53 of the complaint
54. The Defendant Denies allegations in paragraph 54 of the complaint
55. The Defendant Denies allegations in paragraph 55 of the complaint
56. The Defendant Denies allegations in paragraph 56 of the complaint
57. The Defendant Denies allegations in paragraph 57 of the complaint
58. The Defendant Denies allegations in paragraph 58 of the complaint
59. The Defendant Denies allegations in paragraph 59 of the complaint
60. The Defendant Denies allegations in paragraph 60 of the complaint
61. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 61 of the complaint
62. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 62 of the complaint
63. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 63 of the complaint
64. The Defendant lack sufficient knowledge to determined the truth of the allegations in paragraph 64 of the complaint

65. The Defendant Denies allegations in paragraph 65 of the complaint
66. n/a
67. The Defendant Denies allegations in paragraph 67 of the complaint
68. The Defendant Denies allegations in paragraph 68 of the complaint
69. The Defendant denies “Drug” allegation in paragraph 69. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 69 of the complaint
70. The Defendant Denies allegations in paragraph 70 of the complaint
71. The Defendant Denies allegations in paragraph 71 of the complaint
72. The Defendant Denies “Drug” allegations in paragraph 72 of the complaint. The Defendant lack sufficient information to determined the truth of the allegations in paragraph 72 of the complaint

II DEFENSES

Natural supplements are considered food not drugs, there's no where in the law does it says if "Food" treats, cures or prevent it's a "drug". Plaintiff complaint is based on opinions not facts and total disregards to the law they should uphold. A,B and C from multiple sources below defines natural drugs as food and not drugs.

A

Drug use refers to any ingestion of a drug into the body. A drug is generally understood to be any substance, that, when ingested into the body, produces a physiological change. Although food would clearly fit this definition, scholars generally point out that **the definition of drugs does not include food**. Jul 18, 2022



Sage Journals

<https://journals.sagepub.com> › doi › full

[How food is a drug and what food abuse costs - Sage Journals](#)

B

Are dietary supplements considered drugs?

Dietary supplements are regulated by the FDA as food, not as drugs. However, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Dec 21, 2021



fda.gov

<https://www.fda.gov> › consumers › consumer-updates

[Dietary Supplements - FDA](#)

C

Do supplements act as drugs in the body?

Dietary supplements are regulated by the U.S. Food and Drug Administration (FDA) as foods, **not as drugs**. The label may claim certain health benefits. But unlike medicines, supplements can't claim to cure, treat or prevent a disease.



nih.gov

<https://newsinhealth.nih.gov> › 2013/08 › should-you-tak...

[Should You Take Dietary Supplements? - NIH News in Health](#)

FIRST DEFENSE

Earth Tea Products are made from 100% plants and therefore qualifies as a Natural supplement as stated in the Natural Supplement Act of 1994 public law 103-417.

“quote”

§3. Definitions.

- **(a) Definition of Certain Foods as Dietary**

Supplements. Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(ff) The term “dietary supplement” –

- “(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - “(A) a vitamin;
 - “(B) a mineral;
 - “© an herb or other botanical;
 - “(D) an amino acid;
 - “(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - “(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

SECOND DEFENSE

The Complaint states numerous times that anything that treats, prevents, cure or mitigate a disease is a drug.

The above statement is an opinion and recommendation but it's not the law and cannot be found as a policy or rule in the Natural supplement Act

Plaintiff fails to present the federal law or policy that states.

“Any **Dietary Supplement or Food** that treats, cures, prevent or mitigate a disease is a drug.”

The natural supplement law clearly states that statements that are not false or misleading are legal.

The FDA in April 2020 up to December 2021 clearly stated that ‘Dietary supplements are regulated by the FDA and Food not as drugs’ this statement not the “law” changed after my lawsuit. Nevertheless the law is the same. Food is not a Drug

Dietary Supplements

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Dietary supplements are regulated by the FDA as food, not as drugs. However, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. For these reasons, it is important to consult with a health care professional before using any dietary supplement. Read these Consumer Updates to learn more.

Plaintiff accuses Defendant numerous times in the complaint of false advertising, misinformation, deceptive claims, deceptive advertising, incompetent and hurting consumers. Plaintiff fails to present any study or evidence that supports their accusations.

In addition according to the FDA website dated on or before December 2021, natural supplement manufacturer do not have to prove claims or submit any information to the FDA.

How Are Supplements Regulated?

You should know the following if you are considering using a dietary supplement.

- Federal law requires that every dietary supplement be labeled as such, either with the term "dietary supplement" or with a term that substitutes a description of the product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or "calcium supplement").
- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or truthful before it appears on the product.

The law clearly states that Natural supplement manufacturers do not have to

1. Prove effectiveness

2. Prove claims

3. Notify the FDA before marketing or go for sale

4. The FDA website was reviewed before marketing and labeling and the screenshot below shows that I plaintiff did not violate the natural supplement law. Below are content from the FDA website dated back to at least December 2021 before this lawsuit and during the time stated in the complaint

What is FDA's role in regulating dietary supplements versus the manufacturer's responsibility for marketing them?

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Clinton. Before this time, dietary supplements were subject to the same regulatory requirements as were other foods. This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products. Also, manufacturers need to register themselves pursuant to the Bioterrorism Act with FDA before producing or selling supplements. In June, 2007, FDA published comprehensive regulations for Current Good Manufacturing Practices for those who manufacture, package or hold dietary supplement products. These regulations focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

FIFTH EVIDENCE

The Covid-19 Act did not specifically state “Food” was an issue to support the immune system against covid-19

Natural supplement (food) was not mentioned in the covid-19 act nevertheless “Drugs” was mentioned numerous times. Food are not treated as Drugs under federal law and according to the FDA and NIH website, food is not drugs.

Therefore not law was violated with the creation of a successful natural supplement made from ingredients bought legally at food stores.

SIXTH DEFENSE

The plaintiff referred to “Active ingredients” but did provide evidence of active ingredients; neither did the plaintiff provided evidence of why my product contains anything active. All accusations are based on opinions and no facts

SEVENTH DEFENSE

Plaintiff complaint states numerous false and misleading paragraphs with no evidence or facts. Allegations are all opinions, with disregards that there are two laws in the United States of America, there's a (drug) law and a natural supplement (food) law. One requires evidence, testing, registration and is highly regulated (drugs) while the other does not requires evidence, testing and is not highly regulated by the FDA (food). Earth Tea products are food and should be treated as such regardless of its success.

Are herbal supplements considered drugs?

The FDA considers herbal supplements foods, not drugs. Therefore, they are not subject to the same testing, manufacturing, and labeling standards and regulations as drugs. You can now see labels that explain how herbs can influence different actions in the body.



Johns Hopkins Medicine

<https://www.hopkinsmedicine.org> > health > herbal-m... ▼

Herbal Medicine | Johns Hopkins Medicine

III COUNTERCLAIMS

The plaintiff publicly slandered the Defendant instead of alerting Defendant of changes that was required to market and sell a natural supplement such as a disclaimer. Instead the plaintiff made several attempts to publicly defame


the Defendant by labeling Defendant a Fraud and Scam. Immune support is not illegal in the United States of America. Below is an example of numerous immune support products on the market. Earth Tea Extra Strength is marketed as an immune support drink.

Google


immune support products

Images Nature made Airborne Vitapost immune


Sponsored :




Goli Immune Vitamin C
\$14.99
Amazon.com




Emergen-C 1000mg
\$29.19
Amazon.com



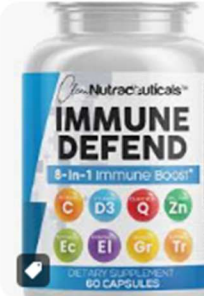
Emergen-C IMMUNE+
\$9.29
CVS Pharmacy
★★★★★ (7k+)




Emergen-C 1,000mg
\$7.79
CVS Pharmacy
★★★★★ (9k+)




AG1 By Athletic Greens
\$99.00
Athletic Greens
★★★★★ (9k+)




Immune Defense Supplement
Amazon.com · In stock



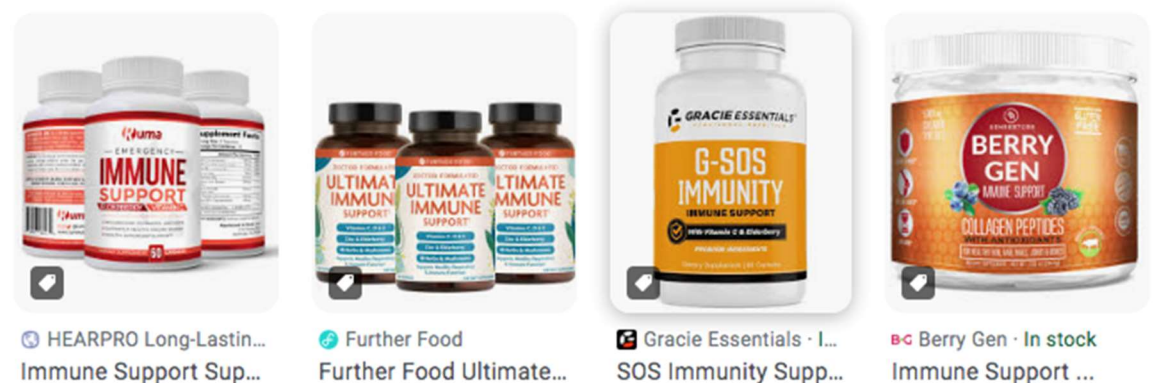
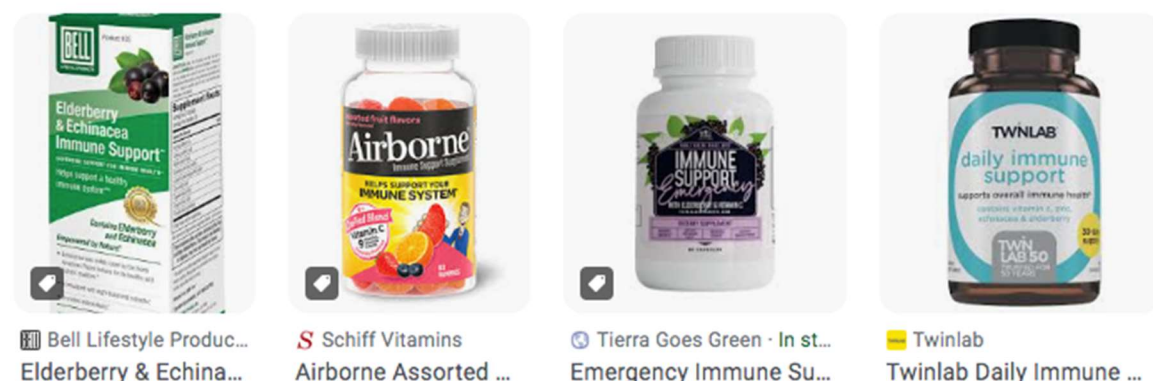
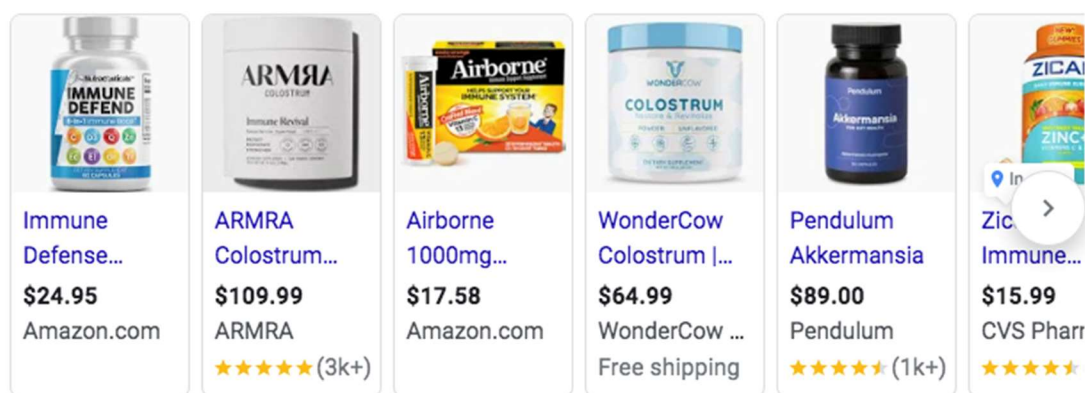
Stamiron Immune Support
Amazon.com · In stock



Rainbow Nutrition Immune Support
Amazon.com · In stock



Nature Made Immune Support
Nature Made · In stock



1. The plaintiff requested multiple platforms to block and ban the Defendant, which resulted in hardship and stress on the Defendant
2. The plaintiff did not follow protocol before filing this lawsuit which is stated in the Natural supplement law Section 403(r) (21 U.S.C. 343(r))
3. The plaintiff abuses power by making decisions to attack Defendant with absolutely no evidence or proof of fraud or misleading statements.
4. Defendant believes systematic racism was used to defame and slander Defendant. Plaintiff did not consult with Defendant before publicly accused Defendant of fraud, scam and deception. Plaintiff first approach to Defendant was outright accusations instead of questions or open dialog.
5. Plaintiff actions brought hardship to Defendant. Public bashing and blocking of almost all platforms and services has cause stress and extreme hardship to Defendant and his family.

Pray for Relief

Monetary Pain and suffering Since March 2022 that the court sees fit

February 6, 2024

/s/ Andrew Sinclair

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